applications, including vascular grafts (including endoluminal stent grafts) and vascular patches for any area of the body. Grafts according to the present invention provide good and physiologic biocompatibility, biostability, compliance, and strength.

In one embodiment of the invention, a vascular graft, such as an AAA stent graft, comprises a core zone or layer comprising a PET fabric. The core zone has a first surface and a second surface opposing the first surface. A non-porous or pore-free coating is disposed on at least the first surface. The coating comprises at least one polyurethane. Preferably the polyurethane is a polyurethane urea, and, most preferably, is THORALON® biomaterial. The coating provides a barrier to prevent fluids from leaking through the pores of the PET fabric core zone. The core zone is preferably configured for use in a vessel having an internal diameter of more than 2 mm, and, more preferably, is configured for use in an abdominal aorta having an internal diameter of more than 6 mm.

Another embodiment of the invention provides a method for sealing the pores of a porous PET graft comprising the step of coating at least one surface of the graft with a polymer composition to produce a pore-free coat on the surface. The graft is preferably configured for use in a vessel having an internal diameter of more than 2 mm and, more preferably, is configured for use in an abdominal aorta having an internal diameter of more than 6 mm. The polymer composition comprises at least one polyurethane. The polyurethanes are segmented and comprise a soft segment and a hard segment. Preferably, the polymer composition is THORALON® biomaterial.

Methods for forming a vascular graft are also provided. For example, another embodiment of the invention provides a method for making a vascular prosthesis comprising the steps of providing a core zone or layer comprising a PET fabric, the core zone having a first surface and a second surface opposing the first surface; and coating at least the first surface of the core zone with a polymer composition to produce a pore-free coat on the surface. As with the previous embodiment, the polymer composition comprises at least one polyurethane and, most preferably, is THORALON® biomaterial. The core zone is preferably configured for use in a vessel having an internal diameter of more than 2 mm. Preferably, the vascular graft is an AAA graft and the core zone is configured for use in an abdominal aorta having an internal diameter of more than 6 mm.

The present invention is directed to vascular grafts made of porous fabrics, such as PET, coated with THORALON® biomaterial or other suitable polyurethanes, to prevent leakage of fluid through the pores of the graft. Specifically, the present invention uses blood-compatible polyurethanes, such as THORALON® biomaterial, as coatings for the blood-contacting textiles. Coated textiles according to the invention have improved impermeability (*i.e.*, are less prone to allow leakage of fluids, such as serum or water, through the body of the graft, both long and short term). The present invention solves the problem of seepage between the graft and aorta through the pores of the fabric occurring with currently available coated PET grafts. The coatings of the invention may be used to coat other grafts, including, but not limited to, ePTFE (expanded polytetrafluoroethylene) grafts.

Because polyurethanes have very low water permeability, they can effectively seal a textile. Furthermore, polyurethanes, such as THORALON® biomaterial, possess a number of desirable properties such as biostability, compliance, biocompatibility, blood compatibility and strength, which are important in many vascular applications. As such, coated textiles according to the invention provide improved blood compatibility, as well as strong and compliant reinforcement or replacement of the diseased area. Accordingly, grafts coated according to the invention may be used in a variety of applications, including vascular grafts, stent grafts and vascular patches. Grafts according to the invention are particularly useful in the repair of AAA.

Grafts according to the invention provide a number of advantages. By using a polymer, preferably a polyether urethane urea such as THORALON® biomaterial, to seal the pores of a woven fabric graft, a blood compatible prosthesis is provided. Graft coatings need to be blood compatible because they come into contact with blood. In addition, the coatings of the invention adhere to the graft, seal the pore openings, and maintain their mechanical function (*e.g.*, prevent seepage between the graft and artery) *in vivo* for a period of years.

The coatings of the invention can perform the necessary sealing function at low thicknesses. Ideally, the profile of a graft must be thin to allow for the smallest possible endolumenal intervention. THORALON® biomaterial has been successfully applied as thinly as 4-5 microns. Depending on the size of the pore which needs to be sealed, even thinner applications may be achieved.

Coatings according to the invention, such as THORALON® biomaterial coatings, not only provide a non-thrombogenic and an improved blood-compatible lumen surface, but may also be used as a drug delivery vehicle *(e.g.,* deliver a pharmacological agent) and as a surface-modifying coating to alter mechanical properties such as compliance and wear resistance. Also, THORALON® biomaterial may be applied as a foam to promote cell adhesion (such as endothelial cells) to form a neointima in all vascular graft applications.

A preferred material for use as a coating according to the invention is THORALON® biomaterial. THORALON® biomaterial is a polyetherurethane urea blended with a siloxane containing surface modifying additive, and has been demonstrated to provide effective sealing of textile grafts. THORALON® biomaterial can be obtained from Thoratec Corporation, Pleasanton, CA. Specifically, THORALON® biomaterial is a mixture of base polymer BPS-215 and an additive SMA-300 in dimethylacetamide (DMAC) solvent. The concentration of additive is preferably in the range of 0.5% to 5% by weight of the base polymer.

The BPS-215 component (Thoratec Corporation, Pleasanton, CA) used in THORALON® biomaterial is a segmented polyether urethane urea containing a soft segment and a hard segment. The soft segment is made of polytetramethylene oxide (PTMO) and the hard segment is made of 4,4'-diphenylmethane diisocyanate (MDI) and ethylene diamine (ED).

THORALON® biomaterial is FDA approved for use in certain vascular applications and has been shown to be safe and effective in a variety of critical applications because it offers thromboresistance, high tensile strength, and superb flex life. THORALON® biomaterial has been shown to be biostable and useful *in vivo* in long term blood contacting applications requiring biostability and leak resistance for periods exceeding one year or more. THORALON® biomaterial has been shown to reduce platelet deposition and binding on blood contacting surfaces of extracorporeal circuits in patients undergoing cardiopulmonary bypass. Because of its flexibility, THORALON® biomaterial is particularly beneficial in larger vessels, such as the abdominal aorta, where elasticity and compliance is essential.

THORALON®['s] biomaterial' lower water absorption contributes to enhanced *in vivo* stability, while its lower critical surface tension and longer Lee White Clotting Times demonstrate improved blood compatibility and thromboresistance (Table 1).

In addition to THORALON®, biomaterial other polyurethane ureas may be used to coat the fabric component of the graft. For example, BPS-215 with a capping ratio (MDI/PTMO mole ratio) ranging from about 1.0 to about 2.5 may be used. Such polyurethane ureas preferably comprise a soft segment, and a hard segment comprising a diisocyanate and diamine. For example, polyurethane ureas with soft segments such as polyethylene oxide, polypropylene oxide, polycarbonate, polyolefin, polysiloxane (*e.g.*, polydimethylsiloxane), and other polyether soft segments made from higher homologous series of diols may be used. Mixtures of any of the soft segments may also be used. The soft segments may also have either alcohol or amine end groups. The molecular weight of the soft segments may vary from about 500 to about 5,000 g/mole, and preferably is about 2,000 g/mole.

In a preferred embodiment, the coating comprises THORALON® biomaterial. However, the coating may comprise one or more polyurethanes, or mixtures and combinations thereof. Preferably, the polyurethanes each comprise a soft segment and a hard segment. As discussed above, the soft segment may comprise one or more compounds selected from the group consisting of polytetramethylene oxide, polyethylene oxide, polypropylene oxide, polycarbonate, polyolefin, polysiloxane (*e.g.*, polydimethylsiloxane), polyether soft segments made from higher homologous series of diols, and mixtures and combinations thereof. The soft segments may also have either alcohol or amine end groups.

Another embodiment of the invention is directed to a method for sealing the pores of a porous PET graft comprising the step of coating at least one surface of the graft with a polymer composition to produce a pore-free coat on the surface, the polymer composition comprising at least one polyurethane, or mixtures and combinations of polyurethanes, as described herein. The graft is preferably configured for use in a vessel or to repair a vessel having an internal diameter of more than 2 mm. More preferably, the vessel has an internal diameter of more than 3 mm, and, most preferably, more than 6 mm. Preferably, the graft comprises an AAA stent graft and the polymer composition comprises THORALON® biomaterial.

The invention is also directed to methods of making PET grafts having reduced permeability. In making such grafts, adhesion of the polyurethane to the textile is a critical parameter. To enhance adhesion, the textile may be pretreated by washing the textile in

methylene chloride, acetone, or another suitable agent. Alternately, additives to the polyurethane may be used to promote effective bonding. Examples include, but are not limited to, THORALON® biomaterial with and without siloxane additive (SMA).

In this example, the water permeability of uncoated graft fabric was compared to fabrics coated with THORALON® biomaterial. Testing was performed in accordance with Association of the Advancement of Medical Instrumentation, ANSI/AAMI VP20, 1994, with the exception of the diameter of the opening, as discussed below. The uncoated fabric tested was made of polyester, and more specifically, was fabric from an AAA graft (AneuRx™ polyester fabric graft, supplied by Medtronic, Inc., Minneapolis, MN). This same fabric was also coated with about a 12 micron layer of THORALON® biomaterial on both sides.

As can be seen from Table 2, there was no flow of water through the THORALON® biomaterial coated fabric, confirming that THORALON® biomaterial coatings can dramatically improve the water permeability of porous graft fabrics.

IN THE CLAIMS:

Please cancel original claim 3, without prejudice.

Please replace original claims 1 and with replacement claims 1 and 46, as follows:

1. (amended) A vascular graft comprising:

a core zone comprising a PET fabric said core zone having a first surface and a second surface opposing said first surface, wherein the first surface is a blood interface surface; and

a first non-porous coating disposed on said first surface and permeating into at least a portion of said core zone, wherein said first coating comprises at least one polyurethane.

46. (amended) A method for repairing a defective vessel in an individual, said vessel having an internal diameter of more than 2 mm, comprising the step of:

reinforcing or replacing said defective vessel with a vascular graft comprising:

a PET fabric core zone, said core zone having a first surface and a second surface opposing said first surface; and

a first non-porous coating disposed on said first surface and permeating into at least a portion of said core zone, wherein said first coating comprises at least one polyurethane.